K120951

OSSTEM IMPLANT

OSSTEM Implant Co., Ltd.

#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

OCT 3 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: August 28, 2012

1. Company and Correspondent making the submission:

- Submitter's Name :	OSSTEM Implant Co., Ltd.
- Address :	#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804, Republic of Korea
- Contact :	Mr. Hee Kwon Son

2. Device :

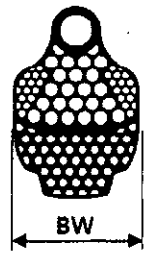
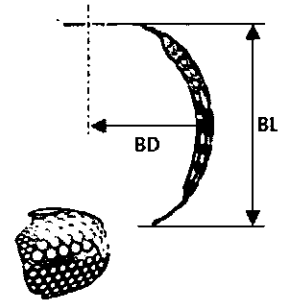
Trade or (Proprietary) Name :	SMARTbuilder System
Classification Name :	Bone Plate 21CFR872.4760 Class II JEY, NHA

3. Predicate Device:

The Neo Titanium mesh, CTi-mem, Neobiotech Co., Ltd., K111761
The SQ IS SYSTEM, Neobiotech Co., Ltd., K090825

4. Description:

Customized 3D Pre-Formed Titanium Membrane. SMARTBuilder is the non-absorbable membrane that is made of titanium metal to stabilize and support of bone graft after bone transplantation at the area having autogenous bone deficiency in the oral cavity.

		Dimensions (mm)
		BW(Buccal width): 8.0, 10.0 BD(Buccal Distance): 5.5 BL(Buccal Length): 7, 9

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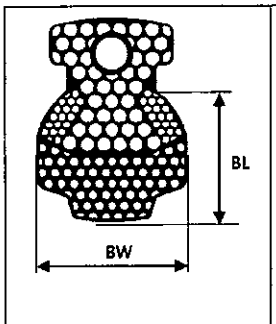
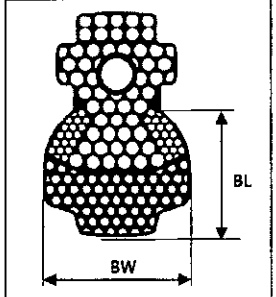
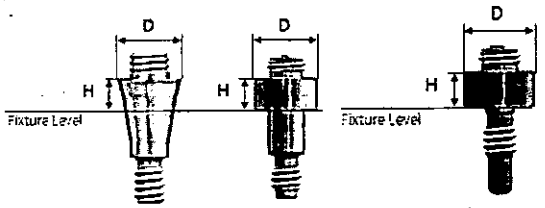
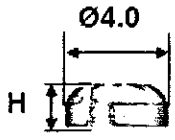
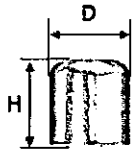
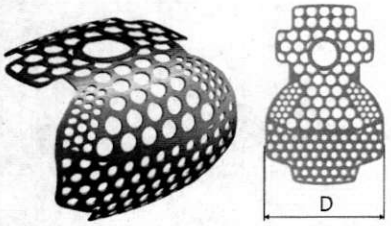
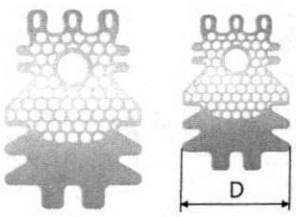
	BW(Buccal width): 9.0, 12.0 BD(Buccal Distance): 5.5 BL(Buccal Length): 7, 9
	BW(Buccal width): 9.0, 12.0 BD(Buccal Distance): 5.5 BL(Buccal Length): 7, 9
	H: 0.5, 1.0, 1.1, 1.5, 2.0, 2.5, 3.0 D: 3.3 ~ 5.03
	H: 1.52
	H: 3.35 ~ 4.22 D: 3.98 ~ 7.0

The SMARTbuilder is made of pure titanium metal and supplied sterile.

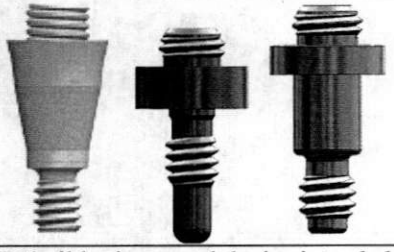
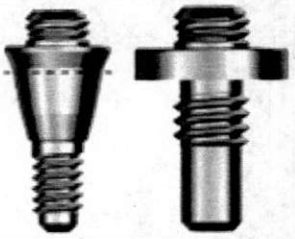
The SMARTbuilder system is used with GS3 System (K091208) of OSSTEM Implant Co., Ltd. and US.SS.GS System (K073247) of OSSTEM Implant Co., Ltd.

The SMARTbuilder is substantially equivalent in design, function and intended use to the Neo Titanium mesh, CTi-mem (K111761) of Neobiotech Co., Ltd
Height, Healing abutment and Cover cap of The SMARTbuilder system are substantially equivalent in design, function and intended use to the SQ IS SYSTEM (K090825) of Neobiotech Co., Ltd

- Substantial Equivalence Matrix

	SMARTbuilder	Predicate devices CTi-mem (K111761)
Design		
Intended use	SMARTbuilder is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	For Stabilization and support bone grafts in dento-alveolar bony defect sites
Material of Fixture	Pure Titanium Grade 2 (ASTM F67)	Pure Titanium Grade 2 (ASTM F67)
Width (D)	8, 9, 10, 12	12
Sterilization	Sterilie	Sterilie
Shelf life	5years	
S E	The SMARTbuilder has same material and indication for use and similar design and technological characteristics as the predicate device, such as the CTi-mem	

	SMARTbuilder System Healing Abutment	Predicate devices SQ IS SYSTEM (K090825) CTi Healing Abutment
Design		
Intended use	SMARTbuilder is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	For Stabilization and support bone grafts in dento-alveolar bony defect sites
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium (ASTM F67)
Diameter	4.0 ~ 7	4.0
Height	3.35 ~ 4.22	3.0, 4.0
Sterilization	Sterilie	Sterilie
Shelf life	5years	
S E	The Healing Abutment has same material and indication for use and similar design and technological characteristics as the predicate device, such as the CTi Healing Abutment	

	SMARTbuilder System Height	Predicate devices SQ IS SYSTEM (K090825) CTi Spacer
Design		
Intended use	SMARTbuilder is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	For Stabilization and support bone grafts in dento-alveolar bony defect sites
Material of Fixture	Titanium alloy Ti 6Al 4V (ASTM F 136)	Pure Titanium (ASTM F67)
Steriliza tion	Sterilie	Sterilie
Shelf life	5years	
S E	The Height has same material and indication for use and similar design and technological characteristics as the predicate device, such as the CTi Spacer	

	SMARTbuilder Cover Cap	Predicate devices SQ IS SYSTEM (K090825) CTi Cover Cap
Design		
Intended use	SMARTbuilder is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	For Stabilization and support bone grafts in dento-alveolar bony defect sites
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium (ASTM F67)
Diameter	4.0	4.0
Height	1.52	1.5
Sterilizati on	Sterilie	Sterilie
Shelf life	5years	-
S E	The Cover Cap has same material and indication for use and similar design and technological characteristics as the predicate device, such as the CTi Cover Cap	

5. Indication for use :
The SMARTbuilder system is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

6. Review :
The SMARTbuilder system has the same material and indication for use and similar design and technological characteristics as the predicate device.

7. Summary of nonclinical testing
Biocompatibility evaluation for SMARTbuilder System is not considered because SMARTbuilder System, which is made with titanium and titanium alloy, has been generally and widely used as a dental material such as implant for a long time

8. Summary of clinical testing
No clinical studies are submitted

9. Conclusion :
Based on the information provided in this premarket notification Osstem Implant Co., Ltd. concludes that the SMARTbuilder system is substantially equivalent to the predicate devices as described herein

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 3 2012

Osstem Implant Company, Limited
C/O Mr. Patrick Lim
Hiossen, Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

Re: K120951
Trade/Device Name: SMARTbuilder System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, NHA
Dated: August 28, 2012
Received: September 12, 2012

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

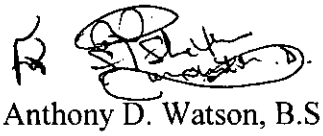
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K 120951

Device Name : SMARTbuilder system

Indication for use : SMARTbuilder System is a metal (Non-resorbable membrane) device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120951